#13

B. Late Applications: Applications that do not meet the criteria in A(1) or A(2) are considered late applications. Late applications will not be considered in the competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description, a copy of the Guidelines for Establishment and Maintenance of Programs, an application package, and business management technical assistance may be obtained from Leah D. Simpson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road NE., room 300, Mailstop E14, Atlanta GA 30305; (404) 842-6594 or FTS 236-6594.

Please refer to Announcement Number 165 when requesting information and submitting any application in response to this announcement.

Programmatic technical assistance may be obtained from:

PSC: R. Louise Floyd, R.N., D.S.N., Project Officer, Program Services and Development Branch, Division of Reproductive Health, Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control, 1600 Clifton Road NE., Mailstop K22, Atlanta, GA 30333; (404) 488-5227 or FTS 236-5227.

PRAMS: Eileen P. Gunter, R.N., M.P.H., Project Officer, Program Services and Development Branch, Division of Reproductive Health, Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control, 1600 Clifton Road NE., Mailstop K22, Atlanta, GA 30333; (404) 488-5227 or FTS 236-5227.

CHIPS: Dan Sadler, M.P.A., Project Officer, Pregnancy and Infant Health Branch, Division of Reproductive Health, Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control, 1600 Clifton Road NE., Mailstop K23, Atlanta, GA 30333; (404) 488-5187 or FTS 236-5187.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report; Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report: Stock No. 017-001-00473-1) through: Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325, Telephone (202) 783-3238.

Dated: August 6, 1991

Robert L. Foster,

Acting Director, Office of Program Support Centers for Disease Control.

[FR Doc. 91-19059 Filed 8-9-91; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 91E-0225]

Determination of Regulatory Review Period for Purposes of Patent Extension; Monopril®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Monopril® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-667) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Monopril®. Monopril® (fosinopril sodium) is indicated for the treatment of hypertension. It may be used alone or in combination with thiazide diuretics. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Monopril® (U.S. Patent No. 4,337,201) from E.R. Squibb and Sons, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated July 2, 1991, advised the Patent and Trademark office that this human drug product had undergone a regulatory review period and that the approval of Monopril® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the regulatory review period for Monopril® is 2,710 days. Of this time, 1,797 days occurred during the testing phase of the regulatory review period, while 913 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: December 16, 1983. The applicant claims December 14, 1983, as the date the investigational new drug application (IND) for Monopril® became effective. However, FDA records indicate that the IND effective date was December 16, 1983.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act: November 15, 1988. FDA has verified the applicant's claim that the new drug application (NDA) for Monopril® (NDA 19-915) was filed on November 15, 1988.

3. The date the application was approved: May 16, 1991. FDA has

verified the applicant's claim that NDA 19-915 was approved on May 16, 1991.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 2 years of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before October 11, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 8, 1991, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 6, 1991.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 91-19118 Filed 8-9-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91E-0224]

Determination of Regulatory Review Period for Purposes of Patent Extension; Orcolon®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Orcolon® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 158(g)(3)(B).

FDA recently approved for marketing the medical device Orcolon®. Orcolon® is indicated for use as a surgical aid in anterior segment surgery, including cataract extraction and intraocular lens implantation. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Orcolon® (U.S. Patent No. Re. 32,969) from Seymour F. Trager and Victoria S. Chylinski. The Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 2, 1991, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Orcolon® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Orcolon® is 1,551 days. Of this time, 1,141 days occurred during the testing phase of the regulatory review period, while 410 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation involving this device was begun: December 31, 1986. The applicant claims October 13, 1986, as the date the investigational device exemption (IDE) became effective. However, FDA records indicate that the IDE was conditionally approved on December 31, 1986.

2. The date an application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: February 13, 1990. The applicant claims July 29, 1987, as the date the premarket approval application (PMA) for Orcolon® (PMA No. P870044) was submitted. However, FDA records indicate that PMA No. P870044 was declared not fileable three times by FDA before being withdrawn by the applicant on June 27, 1988. A second application (PMA No. P900010) was submitted on February 13, 1990 and was accepted by FDA.

3. The date the application was approved: March 29, 1991. FDA has verified the applicant's claim that PMA No. P900010 was approved by FDA on March 29, 1991.

The determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension In its application for patent extension, this applicant seeks 888 days of patent term extension.

Anyone with knowledge that any of the dates are published is incorrect may, on or before October 11, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before February 8, 1992, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.